## Remarks

Reconsideration and withdrawal of the rejections set forth in the Office Action dated March 26, 2002 are respectfully requested. The applicant petitions the Commissioner for a 3-month extension of time. A separate petition accompanies this amendment.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page(s) is/are captioned **"Version with markings to show changes made."**

I. Amendments

The claims are amended in accord with the Examiner's suggestions to correct typographical errors. Specifically, claim 1 is amended to remove the parenthesized word "(define)" and claim 3 is amended to correct the misspellings and to delete the extraneous phrase "wherein the stent". Claim 5 is amended to insert the word "width" after reference to ribbon on line 6 of the claim.

Claim 7 is amended to clarify reference to the stent opening shape "I-beam" (rather than I-beam). Basis for the clarification is found in Figs. 1, 4, 5, and 6.

Claim 8 is amended to delete the extraneous word "stent" in line 1. Basis for the change is found on page 15, lines 9-12.

The specification is amended to correct typographical errors.

Accordingly, these amendments add no new matter.

II. Rejections under 35 U.S.C. §112, second paragraph

Claim 8 was rejected under 35 U.S.C. §112, second paragraph as being indefinite. Specifically, the phrase in line 1 of the claim, "the stent helical ribbon" lacked antecedent basis.

As noted above, claim 8 is amended to delete the extraneous word "stent" in this phrase. Basis for the change is found on page 15, lines 9-12.

Thus, withdrawal of the rejection under 35 U.S.C. §112, second paragraph is resepctfully requested.

III. Rejections under 35 U.S.C. §102

Claim 1 was rejected under 35 U.S.C. §102(b) as allegedly anticipated by Sawyer (U.S. Patent No. 5,108,417). This rejection is traversed for the following reasons.

A. The Invention

The method of treatment set forth in claim 1 includes the following elements:

1. guiding a catheter to a target site;

2. advancing through the catheter a stent having a bending-stiffness gradient along its length due to one or more of

(i) a gradient of ribbon width;

(ii) a gradient of ribbon thickness;

(iii) a gradient of size or number of openings formed in the stent ribbon, and

3. expelling the stent from the catheter at the target site, causing the stent to expand radially against the vessel walls at the target site.

B. The Cited Art

SAWYER describes a stent designed to increase blood flow velocity through the stent without creating turbulent blood flow or areas of stagnant flow. To achieve these goals, the inner surface of the stent is fitted with an airfoil (Col. 3, lines 35-39). In the embodiment illustrated in Fig. 3, the airfoil is composed of individual, staggered segments positioned along the inner stent surface, the segments being progressively thicker. The resulting stent has along its inner surface individual, staggered projections of varying thickness separated by regions that correspond to the thickness of the stent wall.

The stent in Sawyer is delivered to a target site by mounting the stent on the external surface of a delivery catheter prior to catheter insertion into the body. The preassembled stent-catheter system is passed along a guide wire to the target site, where the stent is released from the outer catheter surface (Col. 5, lines 3-8).

C. Analysis

The standard for lack of novelty, that is, for anticipation, is one of strict identity. To anticipate a claim for a patent, a single prior source must contain all its essential elements. M.P.E.P. § 2131.

As noted above, the claimed method includes the steps of (1) guiding a catheter; (2) advancing through the catheter a stent as specifically described; and (3) expelling the stent from the catheter.

Sawyer fails to teach at least element (2) of the present claims, namely the step of "advancing through the catheter a stent" having a bending-stiffness gradient. On Col. 5, lines 3-8, Sawyer describes insertion and deployment of the stent, where a delivery catheter, the stent, and a covering sheath are preassembled and *then* passed along a guide wire to the target site. Nowhere does Sawyer teach the step of "advancing the stent through the catheter" as presently claimed.

Moreover, Sawyer also fails to teach a stent having a bending-stiffness gradient along its length due to (i) a gradient of ribbon width; (ii) a gradient of ribon thickness; and/or (iii) a gradient of size or number of openings in the stent ribbon. As noted above, the stent in Sawyer has an airfoil along the inner stent surface. The airfoil in comprised of individual segments that have varying thickness. While the individual segments of the airfoil exhibit a progression or gradient of thickness, the segments do not form a "ribbon" that has a gradient of thickness, as presently claimed. The stent/airfoil combination in Sawyer has a structure more aptly described as a series of steps consisting of a progression of increasingly (or decreasingly) thick segments steps separated by regions of a constant thickness that is less than the thickness of the thinnest segment.

Thus, Sawyer fails to teach advancing a stent through a catherter and fails to teach a stent have a gradient of ribbon thickness. Accordingly, since the standard of strict identity has not been met, Applicant respectfully requests withdrawal of the rejection of claim1 under 35 U.S.C. §102(b).

IV. Rejections under 35 U.S.C. §103

Claims 2-4 and 8 were rejected under 35 U.S.C. §103 as allegedly obvious over Sawyer in view of Poncet, U.S. Patent No. 5,833,694.

Claims 1, 5, and 6 were rejected under 35 U.S.C. §103 as being obvious over Kropf (U.S. Patent No. 4,760,849) in view of Poncet.

These rejections are respectfully traversed for the following reasons.

A. The Invention

The present invention is described above.

B. The Prior Art

SAWYER is described above.

PONCET describes a method for serial deployment of multiple stents in a patient without having to remove the delivery tool to load on more stents. In the method of Poncet stents are loaded onto the delivery stent "before start of the procedure" (Col. 3, lines 54-56). That is, prior to insertion of the cathether, and prior to guiding the catheter to a treatment site, multiple stents are compressed and placed on the distal end of the catheter sheath. The stent-loaed sheath is then inserted into the passage until the distal end of the sheath is loacted at a first treatment site in the passage (Col. 3, lines 54-58). After deployment of the first stent, the sheath and the other stents are moved to a second treatment site.

KROPF describes a "planar blank" used to prepare a coil spring for implantation into a vessel. The planar blank is an elongated essentially straight member that is wound into a coil spring. The end sections of the planar blank are bent so that the blank forms a "Z-shape", and when in the coiled configuration, the ends of the coil have little to no pitch (Col. 1, lines 44-55). The coil spring formed from the planar blank "forms a spiral lying in one plane having a progressively decreasing radius of curvature"

(Col. 3, lines 54-56). That is, the coil spring when seen in an axial cross-section is radially flattened (Col. 2, lines 25-30).

C. Analysis: Rejection over Sawyer in view of Poncet

According to the M.P.E.P. § 2143.03, "to establish a prima facie case of obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. All words in a claim must be considered in judging the patentability of that claim against the prior art." [citations omitted].

As noted above, the presently claimed method involves the steps of (1) guiding a catheter to a target site; (2) advancing through the catheter the stent specifically described; and (3) expelling the stent from the catheter. Rejected claim 2 requires that the guiding step (1) further include (1a) engaging a pusher wire with the stent, and (1b) pushing the stent through the catheter with the pusher wire.

The Examiner cites Poncet as providing, in Figs. 1-3, a teaching of "a stent being delivered to a vessel with a pusher wire." Poncet on Col. 3, reveals that "[b]efore the start of the procedure, multiple stents are compressed and placed in the dital end of a catheter sheath" (Col. 3, lines 54-58). Thus, the method of Poncet fails to teach step (2) of the present claims, " advancing through the catheter the stent...".

Since the cited references do not teach all of the claimed elements, withdrawal of the rejection based on Sawyer in view of Poncet is respectfully requested.

D. Analysis: Rejection over Kropf in view of Poncet

The Examiner cites Kropf as providing "a method of treating a lesion with a stent having a bending-thickness gradient due to a gradient of ribbon width." The Examiner alleges that Fig. 4 in Kropf shows a "stent" having such a gradient of thickness.

Fig. 4 in Kropf shows a strip of material, termed a "planar blank" by Kropf, for manufacture of a "coil spring." The planar blank shown in Fig. 4 has an elongated, essentially straight midsection and endsections bent in relation to the midsection, to form a blank having a "Z" shape. When the blank is coiled, it forms a *radially flat* spring, where the turns when viewed in a direction perpendicular to the center line of the spring lie in the same plane (Col. 1, line 68 to Col. 2, line 2; Col. 2, lines 25-28; Col.

2, lines 36-41). The end sections are bent so that when the blank is coiled, the ends have a pitch of zero to stabilize anchorage and prevent collapse of the spring (Col. 4, lines 1-6).

The planar blank shown in Fig. 4 has a midsection (11) with less width than the endsections (17, 19). The blank shown in Fig. 1 has an elongated endsection (13) that tapers in width. Kroft states that the purpose of the taper and the width differential is to (1) reduce axial resistance to blood flow and prevent unacceptable deviation of the endpoint (31) as blood flows through the spring (Col. 3, line 62 to Col. 4, line 1) or to (2) enable winding with closer turns to lower pitch (Col. 4, lines 12-16).

Thus, Kropf describes:

1. a *coil spring*, that when viewed in axial cross-section is radially flattened;

2. the coil spring midsection can have a width less than that of the endsections – *e.g.*, the coil spring has a width "differential".

In contrast, the present invention describes a treatment method using a stent, rather than a coil spring. The stent has a bending-stiffness *gradient along its length* due to, for example, a gradient of width. The planar blank shown in Fig. 4 of Kropf has not a gradient of width, but a width *differential* where the middle section is thinner than the two ends.

Thus, Kropf nowhere describes the manufacture of a stent having a gradient of bending-stiffness along its length. The coil spring of Kropf essentially has no "length" dimension (see Figs. 2, 3 of Kropf). The coil spring in Fig. 5 of Kropf is presumably elongated to illustrate the zero pitch end sections and the width differential. Similarly, the planar blank shown in Fig. 1 of Kropf is described as being formed into a radially flat coil, not into a stent having a length dimension.

In summary, the teaching in Kropf with respect to a device differs from the device in the present disclosure in that (1) the device in Kropf is a radially-flat coil spring, rather than an elongate stent, and (2) the planar blank in Kropf has a width differential, rather than a width gradient.

Moreover, Kropf fails to show or suggest the claimed step of advancing through the catheter, a stent. In Kropf, the coil spring is described as being "inserted" or "implanted" transluminally" (Col. 1, lines 9, 13; Col. 3, line 9; Col. 4, line 24) but nowhere describes how the coil spring is implanted, and there is certainly no mention that the coil spring is advanced through a catheter.

Thus, Applicants submit that the teaching in Kropf fails to show or suggest the elements of the stent set forth in the present claims. The secondary reference of Poncet does not provide the missing elements, since, as discussed above, it nowhere shows or suggests (1) advancing a stent through a catheter or (2) a stent having a gradient of *ribbon* width or thickness.

Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §103.

V. Conclusion

In view of the foregoing, the applicant submits that the claims pending in the application comply with the requirements of 35 U.S.C. §112 and patentably define over the cited art. A Notice of Allowance is therefore respectfully requested.

If a telephone conference would expedite prosecution of the application, the Examiner is invited to call the undersigned at (650) 838-4402.

Respectfully submitted,

Date: 9/25/02

Judy M. Mohr
Registration No. 38,563

**Correspondence Address:**
Customer No. 22918
(650) 838-4300

## VERSION WITH MARKINGS TO SHOW CHANGES MADE

Page 3, line 10:

It would therefore be desirable to provide a stent that overcomes these limitations, and which is suitable, in one embodiment, for use in treating neuroaneurysms.

Page 6, line 12:

Fig. 3 is a cross-sectional view of the stent taken through line 3-3 in Fig. 1 that intersects an outer surface region[s] of the stent;

Page 7, line 17:

By bending-stiffness gradient is meant a difference in bending stiffness, as measured by amount or degree of stent bending away from its long axis per force applied; that is, a region of lesser bending stiffness in the stent will exhibit greater bending in response to a given force applied in a direction normal to the stent long axis than a region of greater bending stiffness. In general, and in a preferred embodiment, the stiffness gradient is in a direction of decreasing stiffness on progressing from upstream to the downstream end of the stent, that is, from the more proximal to the more distal stent end, with the stent placed in a catheter. The stiffness gradient may be discontinuous, meaning that the gradient is formed of two [of]or more segments of substantially uniform stiffness, or may be continuous along the length of the stent.

Page 9, line 22:

The wall of the stent can include a plurality of openings disposed along the length of the helical ribbon. The shape of the openings can be round, oval, square, rectangular, diamond, hexagon, or polygon, and the number, size, shape of openings can be varied. A preferred opening is a crossed-beam shape such as an "X", "+", "Z", or "[I]I" shape. Preferably, each opening has one beam axis substantially transverse to

the longitudinal axis of the contracted stent. One beam can be aligned transversely to the other. An example of a shape for the opening is illustrated at 17 in FIG. 1. The openings are "[I]I" shaped whose "[I]I" axis is substantially transverse to the longitudinal axis of the contracted stent. Another example of a suitable opening is shown in FIG. 2 which includes a modified "Z" shaped opening. In FIG. 2, the angle θ between an elongated central portion 15 and a terminal crossed-beam 18 is about 135°C. The openings can be formed using conventional metal working processes such as die and punch, laser cutting, or chemical etching.

Page 13, line 22:

The helical stent is loaded into a catheter as illustrated in FIGs. [9A-9C]10A-10C. The catheter and loaded stent form a device in accordance with another aspect of the invention. The device may additionally include a pusher wire for advancing the stent through the lumen of the catheter, as described below.

Page 17, line 8:

Applicant has determined that a shape which incorporates a "crossed-beam" opening disposed along the length of the helical ribbon, where each opening has at least one beam axis substantially transverse to the longitudinal axis of the stent, has the advantage of facilitating the bending of a stent, in the contracted condition, in both a direction longitudinal to the axis of the stent and in a direction transverse to the longitudinal axis of the stent. For a stent in the expanded condition, such openings minimize the size of the opening, to give greater surface coverage, while maximizing the radial strength of the stent. An example of a preferred opening is an [I]I-beam shaped opening having the "[I]I" axis transverse to the longitudinal axis of the stent in the contracted condition. Another example is a "Z" shaped opening where the central portion of the "Z" is linearly extended and is transverse to the longitudinal axis of the stent in the contracted state.

1. (Amended) A method of treating a lesion at a neurovascular target vessel site, comprising

guiding a neuro-interventional catheter to the target site,

advancing through the catheter, a stent adapted for advancement through a catheter in an upstream to downstream direction to the target site in a contracted stent condition, and with expulsion from the catheter, downstream end first, and radial expansion at the target site, to engage the walls of the vessel,

said stent having a bending-stiffness gradient [(define)] along its length due to one or more of the following:

(i) a gradient of ribbon width;

(ii) a gradient of ribbon thickness;

(iii) a gradient of size or number of openings formed in the stent ribbon, and

expelling the stent from the catheter at the target site, causing the stent to expand radially against the vessel walls at the target site.

3. (Amended) The method of claim 2, [wherein the stent] wherein the stent is [relasably] releasably attached to the pusher wire, for release therefrom, when the stent is released and [extands] extends to its expanded condition.

5. (Amended) The method of claim 1, wherein the stiffness gradient in the stent is due to a gradient of ribbon width, lesser ribbon width at the upstream end of the stent, and greater ribbon width at the downstream end of the stent, where the greater ribbon width is (i) at least ten times the ribbon thickness and (ii) at least two times the lesser width,

said greater ribbon width being effective to reduce the rate of expansion of the stent from its contracted to its radially extended condition, relative to that of a stent having uniform winding widths equal to the lesser ribbon widths,

said lesser ribbon width being effective to increase the angle of catheter bend through which the catheter can be advanced, in an upstream to downstream direction,

relative to that of a stent having uniform winding widths equal to the greater ribbon width.

7. (Amended) The method of claim 1, wherein the stent openings are [I-beam] I-beam shaped openings whose ["I"]"I" axis is aligned transversely to the longitudinal axis of the stent in the contracted state, or Z-shaped openings whose central axis is aligned transversely to the longitudinal axis of the stent in the contracted state.

8. (Amended) The method of claim 1, wherein the [stent] helical ribbon is effective to cover between 50% and 80% of the surface area of the vessel region containing the stent.